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CASE 3-31105A IRW

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October 24, 2005
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
ROSA MARTANI

Art Unit: 1615
Examiner: Tran, Susan

APPLICATION NO: 10/075,429

FILED: FEBRUARY 13, 2002

FOR: RAPIDLY DISSOLVING DOSAGE FORM AND PROCESS FOR MAKING SAME

MS: Appeal Brief- Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Enclosed herewith are three copies of the Appeal Brief in the above-identified application.

☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of $500 for payment of the appeal fee. An additional copy of this paper is here enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-0134 in the name of Novartis.

☐ Enclosed is a Petition for Extension of Time.

Respectfully submitted,

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Date: 10/24/05

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APPELLANT'S BRIEF (37 CFR § 41.31)

Sir:

This brief is in furtherance of the Notice of Appeal, filed on August 25, 2005.

The fees required under §41.20(b)(2), and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief is transmitted in triplicate.

This brief contains these items under the following headings, and in the order set forth below (37 C.F.R. § 41.37(c)).

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments
V. Summary of Claimed Subject Matter
VI. Ground of Rejection to be Reviewed on Appeal
VII. Arguments
VIII. Appendix of Claims
IX. Appendix of Evidence
X. Appendix of Related Decisions

APPELLANT'S BRIEF ON APPEAL

I. Real Party in Interest

The real party in interest in this application is Novartis AG, a company organized under the laws of the Swiss Confederation, having a place of business at Lichtstrasse 35, Basel, Switzerland.

II. Related Appeals and Interferences

There are not any related appeals or interferences which will directly affect, or be directly affected by, or have a bearing on, the Board's Decision in this Appeal.

III. Status of Claims

This is an Appeal from the Final Rejection of Claims 1-11 and 13-27. Claims 13-26 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-15 of Humbert-Droz et al. U.S. Pat. No. 6,083,531 in view of Bovenkerk et al. U.S. Pat. No. 4,311,490. Claims 1-11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable Humbert-Droz et al. WO 97/38679. Claims 13-26 are rejected under 36 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679 in view of Erodes et al. U.S. Pat. No. 5,108,757. Claims 13-26 are also rejected under 36 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679 in view of Bovenkerk et al. U.S. Pat. No. 4,311,490.

There are no allowed claims and claim 12 was cancelled. Claims 1-11 and 13-27 are pending in this Appeal.

IV. Status of Amendments

No amendment after final rejection was filed.

V. Summary of Claimed Subject Matter

The invention is directed to a solid dosage form that is designed to rapidly disintegrate in an aqueous medium and a process of making the solid dosage form. The solid dosage form contains an active ingredient, a disintegrant, and other ingredients. The

dosage form is produced by making a compacted unit, which contains all the ingredients or all the ingredients other than the active for the dosage form, dispensing a solvent or solvent with the active in a mold or cavity, and then placing the compacted unit in the mold or cavity. The solvent is then removed to produce a solid dosage form that is designed to rapidly disintegrate in an aqueous medium, for example, saliva in the mouth. *See*, Specification, page 2, line 20 - page 3, lines 15, and page 1, lines 1 to 12.

VI. Grounds of Rejection to be Reviewed on Appeal

A. Whether Claims 13-26 are rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-15 of U.S. Pat. No. 6,083,531 in view of U.S. Pat. No. 4,311,490.

B. Whether Claims 1-11 and 27 are unpatentable under 35 U.S.C. 103(a) over Humbert-Droz et al. WO 97/38679.

C. Whether Claims 13-26 are unpatentable under 35 U.S.C. 103(a) over Humbert-Droz et al. WO 97/38679 in view of U.S. Pat. No. 5,108,757.

D. Whether Claims 13-26 are unpatentable under 35 U.S.C. 103(a) over Humbert-Droz et al. WO 97/38679 in view of U.S. Pat. No. 4,311,490.

VII. Arguments

A. Obviousness Type Double Patenting Rejection

Claims 13-26 are rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-15 of Humbert-Droz et al. U.S. Pat. No. 6,083,531 ('531) in view of Bovenkerk et al. U.S. Pat. No. 4,311,490 (Bovenkerk). For clarification purposes, Appellant notes that Humbert-Droze et al. WO 97/38679 is the PCT priority document of the '531 patent. Appellants submit that a rejection under the judicially created doctrine of obviousness type double patenting can only be supported if an obviousness rejection under 35 U.S.C. 103 can be established.

The Examiner stated that "[A]although the conflicting claims are not identical, they are not patentably distinct because '531 claims a solid pharmaceutical dosage form comprising active substance, filler, binding agent and usual auxiliaries." The Examiner further stated that Bovenkerk discloses a binder such as polymethylmethacrylate, and therefore, one skilled in the art would expect a similar quick dissolve dosage form. It is also

stated that there are no unusual and/or unexpected results, which would rebut *prima facie* obviousness.

Appellants respectfully submit that a *prima facie* case of obviousness cannot be established with the references cited by the Examiner, and thus, Appellants do not have to consider any evidence to rebut a *prima facie* case of obviousness. The burden is first on the Patent Office to establish a *prima facie* case of obviousness. MPEP §2143 states a *prima facie* case of obviousness can only be established when three basic criteria are met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. The MPEP section clearly indicates that the prior art must suggest the desirability of the claimed invention and the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. First, Appellants submit that there is no suggestion or motivation to modify or combine teachings of the cited references. Second, Appellants submit that there is no expectation of success. Accordingly, Applicants submit that the Patent Office has not established a *prima facie* case of obviousness.

First, there is no suggestion or motivation to modify the composition of '531 and combine reference teachings. Both '531 and Bovenkerk do not disclose or teach any disintegrant. On the other hand, both '531 and Bovenkerk disclose binders. However, a binder and a disintegrant provide highly different functions and utilities. A binder holds ingredients in a composition together. In contrast, a disintegrant facilitates disintegration of ingredients in a composition. The Examiner indicated that Bovenkerk teaches polymethylmethacrylate. However, Bovenkerk uses polymethylmethacrylate as a binder, whereas the present invention may use polymethylmethacrylate as a disintegrant in a solid dosage form that disintegrates, for example, in the mouth. It is well known that one compound or substance can provide two or more different functions depending on the manner of use or configuration of the compound, especially in the chemical field. As a simple example, iron can be used to form a shield, and iron can also be used to produce a projectile to defeat the shield. Appellants submit that it is not reasonable to conclude that a disclosure of a binder teaches or suggests a disintegrant even when the two ingredients are produced from one raw material. Appellants submit that the initial burden is on the Patent Office to provide at least some evidence to support the allegation that binders and integrants are interchangeable ingredients and, therefore, a disclosure of a binder provides a motivation to use the binder as a disintegrant.

Moreover, Bovenkerk teaches that its binder, i.e., polymethylmethacrylate, is a distillable fugitive binder that is removed under vacuum in an oven. See, column 5, lines 2-8, of '490. There hardly is any suggestion or motivation that a binder which is removable in an oven under vacuum is useful as a disintegrant in a medicinal dosage form that disintegrates in the mouth. Appellants submit that the Patent Office has not demonstrated that there is any suggestion or motivation to modify the composition of '531 or combine isolated teachings of the cited references.

Second, there is no expectation of success. As discussed above, '531 does not disclose a disintegrant. Although '531 is directed to a composition that disintegrates, there is no disclosure of any disintegrant in '531. Accordingly, an expectation of success needs to come from Bovenkerk. However, Bovenkerk only teaches a binder that is removed in an oven under vacuum, i.e., polymethylmethacrylate. There cannot be any expectation of success to use a binder, which is removed in an oven under vacuum, as a disintegrant in a medicinal dosage form, which is designed to disintegrate in an aqueous medium. Appellants submit that when there is no disclosure or suggestion of any disintegrant in either of the cited references and there only is a disclosure of binder that needs to be removed by an arduous process, there cannot be any expectation of success.

Appellants submit that the initial burden of establishing a *prima facie* case of obviousness is on the Patent Office and that a *prima facie* case of obviousness has not been established since at least two of the three requirements for establishing a *prima facie* case of obviousness have not been met, i.e., no showing of suggestion for modification and no showing of expectation of success. Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the rejection under the judicially created doctrine of obviousness type double patenting since the Patent Office has not established a *prima facie* case of obviousness.

B. 35 U.S.C. 103(a) Rejection over Humbert-Droz et al. WO 97/38679

Claims 1-11 and 27 are rejected 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. (WO 97/38679), which is referred to as Humbert-Droz hereinafter. The pending claims are directed to a process for producing a solid dosage form that rapidly disintegrates in an aqueous medium.

The Examiner stated that Humbert-Droz is silent as to the teaching of compacting the powder or granulate as claimed in step (c). The Examiner further stated that it would have been obvious for one of ordinary skill in the art to modify Humbert-Droz with

the expectation of similar result because Humbert-Droz teaches a rapidly dissolving dosage form having a similar density.

Appellants respectfully submit that a *prima facie* case of obviousness has not been established since there is no evidence in record to indicate that the current process that contains a compacting step is suggested by Humbert-Droz and since no expectation of success can be found in Humbert-Droz. As discussed above, MPEP §2143 states a *prima facie* case of obviousness can only be established when the three basic criteria are met.

Appellants submit that the processes disclosed by Humbert-Droz and the present invention are highly different processes although the two processes produce dosage forms that have fast dissolving characteristics. As indicated by the Examiner, Humbert-Droz does not teach that a compacting step is utilized in its process. For example, claim 1 of Humbert-Droz clearly indicates that its claimed dosage form is produced without a compacting step. Appellants submit that it is not proper to conclude that two different processes are similar merely because there are similarities in the disintegrating properties of the end products. In general, Humbert-Droz teaches a process that initially suspends or dissolves all of the ingredients of the dosage form in a solvent, and then dries the suspension or solution in a mold to form a sold dosage form. In contrast, the process of the present invention has the steps of compacting all ingredients or all but the active ingredient in their solid form to produce a cohesive solid unit, placing the compacted cohesive unit in a solvent, and then removing the solvent to produce a solid dosage form. Because the present process uses a disintegrant, the compacted unit containing the ingredients can be merely placed in a solvent to wet the compacted unit and then dried to produce a solid dosage form that rapidly disintegrates in an aqueous medium, such as, saliva in the mouth. In addition, the ingredients are compacted to form a cohesive solid unit first, the amount of solvent needed to produce a solid dosage form with a physical integrity is greatly reduced. And, thus, there requires significantly less time to produce the dried final product. In contrast, Humbert-Droz process dissolves or suspends all of its ingredients in a solvent first and then places the solution or suspension in a mold. The solution or suspension is then dried to produce a solid dosage form. Clearly, the process of the present invention has at least two steps that are different from the process of Humbert-Droz. One, the present process does not have the initial step of dissolving or suspending all the ingredients in a solvent, and two, the present process compacts the ingredients for the dosage form to a cohesive unit.

There is no suggestion or motivation in Humbert-Droz that its process can be or should be modified to include a compacting step. When there is no suggestion of a compacting step in Humbert-Droz, there cannot be any expectation of success for a process that contains a compacting step. The Examiner does not provide any evidence to support

the conclusion that it is obvious to include a compacting step in Humbert-Droz, other than a conclusory statement that it would have been obvious. Appellants submit that without more, Humbert-Droz does not make the present invention *prima facie* obvious since Humbert-Droz does not suggest or provide any motivation to modify its process, and since it does not provide any expectation of success.

Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the rejection under 35 U.S.C. 103(a) over Humbert-Droz since at least two of the three criteria required to establish a *prima facie* case of obviousness have not been met.

C. 35 U.S.C. 103(a) Rejection over Humbert-Droz et al. (WO 97/38679) in view of Erodes et al. (U.S. 5,108,757)

Claims 13-26 are rejected 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz in view of Erodes et al. US 5,108,757 (Erodes). Humbert-Droz was cited for its teaching of a fast disintegrating dosage form. The Examiner stated that Humbert-Droz does not teach disintegrants. Erodes was cited for its teaching of known auxiliary agents, including talc, magnesium stearate, and croscarmellose. The Examiner stated that Erodes is solely relied upon for the teaching of known auxiliary agents in tablet dosage form.

Appellants submit that a *prima facie* case of obviousness has not been established since there is no suggestion or motivation to combine the two cited references. Humbert-Droz does not teach that its composition contains a disintegrant, although it teaches that its composition can contain other auxiliary ingredients. Erodes is directed to a tablet that is not fast disintegrating and has two portions. Erodes teaches at column 2, lines 36-40, "[T]the term "relatively quick release pharmaceutical composition" used throughout the specification relates to compositions from which 50% of the active ingredient is released within a period not exceeding one hour..." Otherwise, even the quick release portion of the composition of Erodes only release 50% of the active in about one hour. Erodes does not teach any rapidly orally disintegrating tablet. Appellants submit that a *prima facie* obviousness cannot be established by arbitrarily combining one teaching that an oral disintegrating tablet can contain one or more of auxiliary ingredients selected from many different auxiliary ingredients with another isolated teaching that an auxiliary ingredient can be a disintegrant. This is nothing more than picking and choosing isolated elements from prior art references in a hindsight analysis based solely on the Appellants' own disclosure and guidance. This is not a standard that can be properly used to establish a *prima facie* case of obviousness. Humbert-Droz does not teach or suggest any disintegrant in a oral

disintegrating dosage form. There is no teaching or suggestion of specific desirability of using any one specific auxiliary ingredient, especially not a disintegrant, in Humbert-Droz. As for Erodes, as indicated by the Examiner, Erodes is cited to indicate that a disintegrant is known. Erodes merely teaches that a disintegrant is known in the art and a disintegrant can be used in a tablet that is designed to release its active compound some time after the tablet is ingested. Erodes does not provide any motivation or suggestion that a disintegrant can be used to provide rapid and complete disintegration of an orally disintegrating dosage form.

Again, Appellants submit that a *prima facie* case of obviousness can only be established when the three basic criteria are met. Appellants submit that, first, there is no suggestion or motivation to modify the composition of Humbert-Droz. As discussed above, Humbert-Droz does not teach or suggest any disintegrant, and, therefore, there is no motivation or suggestion in Humbert-Droz that its composition can be modified to include a disintegrant. As for Erodes, it is the Examiner's contention that the reference is cited merely for the fact that a disintegrant is known, and, again, there is no suggestion or motivation given in Erodes to modify the composition of Humbert-Droz. Appellants submit that the Patent Office has not provided any teaching or evidence that the composition of Humbert-Droz can be modified for any reason. Just because an isolated ingredient can be picked from a reference and added to a prior art composition does not make the invention obvious, unless there is a teaching or suggestion that adding the isolated element is desirable.

Second, there is no expectation of success. Since neither Humbert-Droz nor Erodes provides any motivation to modify the composition of Humbert-Droz, there cannot be any expectation of success for the unique composition of the present invention.

Appellants submit that a *prima facie* case of obviousness has not been established and request that the Board of Patent Appeals and Interferences reverse the rejection under 35 U.S.C. 103(a) over Humbert-Droz in view of Erodes.

D. 35 U.S.C. 103(a) Rejection over Humbert-Droz et al. (WO 97/38679) in view of Bovenkerk et al. (U.S. 4,311,490)

Claims 13-26 are rejected 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz in view of Bovenkerk et al. US 4,311,490 (Bovenkerk). Humbert-Droz was cited for its teaching of a fast disintegrating dosage form. However, the Examiner stated that Humbert-Droz does not teach disintegrants. Bovenkerk was cited for the teaching that polymethylmethacrylate is a known binding agent.

Appellants submit that a *prima facie* case of obviousness has not been established since there is no motivation to combine the references and there is no expectation of success.

As discussed above, Humbert-Droz does not teach any disintegrant, and Humbert-Droz does not provide any suggestion or motivation that its composition can be modified. Accordingly, any suggestion or motivation to modify should come from Bovenkerk. However, Bovenkerk also does not teach any disintegrant. Bovenkerk merely teaches that polymethylmethacrylate can be used as a binder to hold abrasive materials together. In contrast, the present invention may use polymethylmethacrylate as a disintegrant to make the dosage form to disintegrate rapidly in an aqueous medium, such as saliva in the mouth. Appellants submit that a teaching of using a material to hold other materials together cannot make obvious the use of the same material to do exactly the opposite, i.e., disintegrate or disperse other materials. There is no motivation to use the binder, which is used to produce an abrasive tool taught by Bovenkerk, as a disintegrant in a disintegrating pharmaceutical dosage form. Appellants submit that there is no suggestion or motivation to modify the composition of Humbert-Droz and no motivation to combine the teachings of the two references.

Since neither Humbert-Droz nor Bovenkerk provides any motivation to modify the composition of Humbert-Droz, there cannot be any expectation of success for the unique composition of the present invention.

Appellants submit that a *prima facie* case of obviousness has not been established and request that the Board of Patent Appeals and Interferences reverse the rejection under 35 U.S.C. 103(a) over Humbert-Droz in view of Erodes.

In summary, for the reasons set forth above, reversal of the rejections is respectfully requested.

VIII. Appendix of Claims

1. A process for the manufacture of a solid dosage form which is rapidly dissolving in aqueous medium, wherein the solid dosage form comprising an active substance and other pharmaceutical ingredients suitable for a solid dosage and wherein the solid dosage form is a pharmaceutical or veterinary dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of
(1) either the active substance or part thereof and the other pharmaceutical ingredients of the solid dosage form, or
(2) the other pharmaceutical ingredients of the solid dosage form;

(b) dispensing
(1) either an auxiliary solvent, if (a)(1) includes all of the active substance, or
(2) a solution or dispersion of the active substance in an auxiliary solvent,
in cavities of a pre-formed container intended for storage of the solid dosage form or molds;

(c) compacting a suitable amount of the powder or granulate prepared according to (a)(1) or (a)(2) above;

(d) putting the compacted powder or granulate prepared according to (c) on the top of the solvent which according to (b)(1) or (b)(2) is in the molds or in the cavities of the pre-formed container intended for storage of the solid dosage form;

(e) removing the auxiliary solvent by applying a drying system to the molds or the cavities of the pre-formed container intended for storage of the solid dosage form after (d); and

(f) removing the dried solid dosage form from the molds into a suitable storage container or sealing the cavities of the pre-formed container intended for storage of the solid dosage form, respectively.

2. A process according to claim 1 for the manufacture of a solid, rapidly dissolving pharmaceutical or veterinary dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of
(1) either the intended dose of the active substance or part thereof and the other pharmaceutical ingredients of the solid dosage form, or
(2) the other pharmaceutical ingredients of the solid dosage form;

(a') transferring the powder or granulate to a combined compacting/dosing system; and

(a") placing the molds or the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form within the operating range of the combined compacting/dosing system;

(b) dispensing,
(1) either an auxiliary solvent, if (a)(1) includes all of the active substance, or
(2) a solution or dispersion of the active substance in an auxiliary solvent,
in the molds or in the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form;

(c) compacting - within the combined compacting/dosing system - a suitable amount of the powder or granulate prepared according to (a)(1) or (a)(2) above;

(d) putting the compacted powder or granulate on the top of the liquid which according to (b)(1) or (b)(2) is in the molds or in the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form;

(e) removing the auxiliary solvent by applying a drying system comprising one or more techniques selected from the group consisting of forced warm gas, microwave radiation and reduced pressure, to the units in the moulds or in the cavities of the pre-formed container intended for storage of the solid dosage form; and

(f) removing the dried units from the moulds into a suitable storage container or sealing the cavities of the pre-formed container intended for storage of the solid pharmaceutical or veterinary dosage form, respectively.

Claim 3 (previously presented): A process according to claim 1 for the manufacture of a solid, rapidly dissolving pharmaceutical dosage form for oral administration, which process comprises

(a) preparing a powder or granulate consisting of the active substance and the other pharmaceutical ingredients of the solid dosage form;

(a') transferring the powder or granulate to a combined compacting/dosing system;

(a") placing a pre-formed container intended for storage of the solid pharmaceutical dosage form within the operating range of the combined compacting/dosing system;

(b) dispensing an auxiliary solvent in the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form;

(c) compacting - within the combined compacting/dosing system - an amount of the powder or granulate prepared according to (a) above, which amount of powder or granulate contains the intended dose of the active substance;

(d) putting the compacted powder or granulate on the top of the liquid which according to (b) is in the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form;

(e) removing the auxiliary solvent by applying a drying system comprising at least two different techniques selected from the group consisting of forced warm gas, microwave radiation and reduced pressure; and

(f) sealing the cavities of the pre-formed container intended for storage of the solid pharmaceutical dosage form.

4. A process according to claim 1, where in step (b) the auxiliary solvent is selected from the group consisting of water, ethanol, acetone, isopropanol and any mixtures thereof.

5. A process according to claim 1, where in step (c) the density of the compacted powder or granulate prepared is between 300 and 1000 mg/ml.

6. A process according to claim 1, where in step (c) the density of the compacted powder or granulate is between 400 and 900 mg/ml.

7. A process according to claim 1, where in step (c) the amount of powder or granulate which is subjected to compaction contains the intended dose of the active substance.

8. A process according to claim 1, where in step (e) the auxiliary solvent is removed by applying simultaneously or sequentially at least two different techniques selected from the group consisting of forced warm gas, microwave radiation and reduced pressure.

9. A process according to claim 1, where in step (e) the auxiliary solvent is removed by applying simultaneously a combination of forced warm gas and microwave radiation.

10. A process according to claim 1, wherein a solid pharmaceutical or veterinary dosage form for oral administration is manufactured.

11. A process according to claim 10, wherein a solid pharmaceutical dosage form for oral administration which is in the form of a tablet is manufactured.

13. A solid dosage form which is rapidly dissolving in aqueous medium, comprising
(1) a pharmaceutically or veterinary active substance,
(2) a filler selected from the group consisting of mannitol, lactose, calcium phosphates, dibasic calcium phosphates, microcrystalline cellulose, cyclodextrine, starch, laevulose, maltitol, polydextrose, sucrose, glucose, inulin, sorbitol or xylitol, and
(3) a disintegration agent selected from the group consisting of croscarmellose Na; sodium glycolates of starches, cross-linked poly-N-vinyl-2-pyrrolidones, polymethylmethacrylates, soy polysaccharides or synthetic resins.

14. A solid dosage form according to claim 13, comprising
(1) a pharmaceutically or veterinary active substance, and
(2) mannitol, lactose, starch and microcrystalline cellulose.

15. A solid dosage form according to claim 13, consisting essentially of a homogeneous mixture of
(1) at least one pharmaceutically or veterinary active substance,
(2) at least one filler,
(3) at least one disintegration agent, and
(4) optionally pharmaceutically or veterinarily acceptable excipients,
which dosage form disintegrates when taken into the mouth within 30 seconds, and

which dosage form has a density of 400-900 mg/ml.

16. A solid dosage form according to claim 15, consisting essentially of a homogeneous mixture of
(1) at least one pharmaceutically active substance,
(2) at least one filler selected from the group consisting of mannitol, lactose, calcium phosphates, dibasic calcium phosphates, microcrystalline cellulose, cyclodextrine, starch, laevulose, maltitol, polydextrose, sucrose, glucose, inulin, sorbitol or xylitol,
(3) a disintegration agent, and
(4) optionally pharmaceutically acceptable excipients.

17. A solid dosage form according to claim 15, consisting essentially of a homogeneous mixture of
(1) a pharmaceutically or veterinary active substance,
(2) mannitol,
(3) a disintegration agent; and
(4) optionally pharmaceutically excipients.

18. A solid dosage form according to claim 13, wherein the active substance is selected from the group consisting of (a) diclofenac, ketoprofen, ibuprofen, aspirin, paracetamol, melatonin and pharmaceutically acceptable salts thereof, and (b) pharmaceutically acceptable salts of calcium, magnesium and zinc.

19. A solid dosage form according to claim 15, wherein the composition contains as one of the excipients (4) a lubricant.

20. A solid pharmaceutical or veterinary dosage form for oral administration according to claim 19, wherein the lubricant is talc.

21. A solid dosage form according to claim 15, wherein the composition contains as the excipients (4) comprising a lubricant, and one or more sweeteners.

22. A solid dosage form according to claim 13, wherein the filler (2) is present in an amount of at least 30 weight-%, and the disintegrating agent (3) is present in an amount of from 0.5 up to 15 weight-% of the total dosage form.

23. A solid dosage form according to claim 15, which dosage form is manufactured without applying any compression force to the mixture of the components (1), (2), (3) and optionally (4) during the last step of manufacture concerning the solid dosage form.

24. A solid dosage form according to claim 13, which dosage form is manufactured without applying any freeze-drying process.

25. A solid dosage form according to claim 15, which dosage form is manufactured by starting with the preparation of a homogeneous mixture of all the components (1), (2), (3) and optionally (4) of the dosage form.

26. A solid dosage form according to claim 13, which is intended for the pharmaceutical field.

27. A process for the manufacture of a solid dosage pharmaceutical composition which rapidly dissolves in an aqueous medium, comprising the steps of
(a) preparing solid powder or granule forms of ingredients for the solid dosage composition, the ingredients including an active substance;
(b) compacting a suitable amount of the ingredients including none, some or all of the active substance;
(c) dispensing in a mold or a cavity of a pre-formed container intended for storage of the solid dosage composition either an auxiliary solvent or an active substance-containing auxiliary solvent if the compacting step (b) does not include all of the active substance, wherein the active substance-containing auxiliary solvent is a solution or suspension of the active substance in the auxiliary solvent;
(d) placing the compacted solid ingredients in the mold or cavity; and
(e) removing the auxiliary solvent from the mold or cavity to form the solid dosage composition after the compacted solid ingredients and the auxiliary solvent with or without the active substance are placed therein.

IX. Appendix of Evidence

None

X. Appendix of Related Decisions

None

Respectfully submitted,

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Date: October 24, 2005